K043318

DEC 23 2004

510(k) Summary - Elecsys® Folate II

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence

Submitter name, address, contact

Roche Diagnostics
9115 Hague Rd
Indianapolis IN 46250
(317) 521-3544

Contact person: Kay A. Taylor

Date prepared: December 1, 2004

Device Name

Proprietary name: Roche Elecsys® Folate II Immunoassay

Common name: Folate Assay

Classification name: Acid, Folic, Radioimmunoassay

Device description

The Elecsys Folate II Assay employs a competitive test principle. In the first step, bound folate in the sample is released from endogenous folate binding proteins through incubation with pretreatment reagents. In the second step, ruthenium labeled folate binding protein complexes with the sample. In the third step, after the addition of streptavidin-coated microparticles and folate labeled with biotin, the unbound sites of the ruthenium labeled folate binding protein become occupied, with formation of a ruthenium labeled folate binding protein-folate biotin complex. The complex becomes bound to the solid phase. The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode, unbound substances are removed. Voltage is applied to the electrode inducing chemiluminescent emission which is measured by a photomultiplier. Results are determined using a calibration curve that is generated specifically on each instrument by a 2 point calibration and a master curve provided with the reagent bar code.

510(k) Summary - Elecsys® Folate II, continued

Intended use

Binding assay for the in vitro quantitative determination of folate in human serum. The binding assay is intended for use on the Roche Elecsys 2010 and MODULAR ANALYTICS E170 (Elecsys module) immunoassay analyzers.

Predicate Device

We claim substantial equivalence to the Elecsys Folate II Immunoassay currently marketed on the MODULAR ANALYTICS E170. (K031756).

Device Comparison

The table below illustrates the similarities between the Elecsys Folate II (K031756) and the Elecsys Folate II (modified device).

Topic	Elecsys® Folate II (K031756)	Elecsys® Folate II (Modified Device)
Intended Use	Binding assay for the in vitro quantitative determination of folate in human serum. The binding assay is intended for use on the Roche Elecsys 2010 and MODULAR ANALYTICS E170 (Elecsys module) immunoassay analyzers.	Binding assay for the in vitro quantitative determination of folate in human serum. The binding assay is intended for use on the Roche Elecsys 2010 and MODULAR ANALYTICS E170 (Elecsys module) immunoassay analyzers.
Indications for Use	Measurements obtained by this devices are used in the diagnosis and treatment of anemias of the gastrointestinal malabsorption.	Measurements obtained by this devices are used in the diagnosis and treatment of anemias
Test Principle	Competitive chemiluminescence	Same
Sample Type	Serum	Same
Expected Values	3.1-17.5 ng/ml	Same
Measuring range	0.600-20.00 ng/ml	Same

510(k) Summary - Elecsys® Folate II, continued

Topic	Elecsys® Folate II (K031756)	Elecsys® Folate II (Modified Device)
Traceability	Standardized against Elecsys Folate which was itself standardized against a commercially available radiobinding folate assay.	Standardized against Elecsys Folate.
Stability	Store at 2-8°C unopened up to the expiration date. Opened: At 2-8°C for 12 weeks On E170 / 2010 for 6 weeks	Same Opened: Same On E170 / 2010 for 1 week

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 23 2004

Ms. Kay A. Taylor MT (ASCP), RAC
Regulatory Affairs Principal
Roche Diagnostics Corp.
Centralized Diagnostics
9115 Hague Rd.
PO Box 50457
Indianapolis, IN 46250-0457

Re: k043318
Trade/Device Name: Roche Elecsys Folate II Immunoassay
Regulation Number: 21 CFR 862.1295
Regulation Name: Folic acid test system
Regulatory Class: Class II
Product Code: CGN
Dated: December 1, 2004
Received: December 2, 2004

Dear Ms. Taylor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Carol C. Benson for

Cornelia B. Rooks, MA
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

DEC 1 7 2004

Indications for Use

510(k) Number (if known): **K043318**

Device Name: **Roche Elecsys Folate II Immunoassay**

Indications For Use:

Binding assay for the in vitro quantitative determination of folate in human serum. Measurements obtained by this devices are used in the diagnosis and treatment of anemias.

The binding assay is intended for use on the Roche Elecsys 2010 and MODULAR ANALYTICS E170 (Elecsys module) immunoassay analyzers.

Prescription Use XX AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K043318